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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/187,669	11/05/1998	EDUARDO MARBAN	47728	3339

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EDWARDS & ANGELL, LLP  
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BOSTON, MA 02205

EXAMINER

LEFFERS JR, GERALD G

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 05/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/187,669

Applicant(s)

MARBAN, EDUARDO

Examiner

Gerald G. Leffers Jr., PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 January 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 32-36 and 38-64 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 32-36 and 38-64 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Amendment***

Receipt is acknowledged of an amendment, filed 1/21/2005, in which several claims were amended (claims 32, 38, 40, 44 and 46-60) and in which claim 37 was cancelled. Claims 32-36 and 38-64 are pending and under consideration in the instant application.

Any rejection of record not addressed herein is withdrawn. It is noted that applicant's response is technically incomplete in that it does not specifically address the rejection of record under 35 U.S.C. 103(a) and in that it does not point to where in the originally filed specification and claims there is support for amended claim 46. In the interest of expediting prosecution, the examiner has not sent out a Notice of Nonresponsive Amendment on these grounds. In the future, it is requested that applicant's representative address each of the rejections of record and provide a specific citation from the originally filed specification and claims for support for each amendment of the claims that is presented. This action is FINAL.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 32-36 and 38-64 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the

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claimed invention. **This is a new rejection that is necessitated by applicant's amendment of the claims in the response filed on 1/21/2005.**

Claim 32 has been amended to include the new limitation "... (c) analyzing the result of expression of the modulated protein by correlating the result of expression of the modified protein to the result of expression of a corresponding native protein...". The response filed on 1/21/2005 points to the specification at page 5, lines 17-24 for support for the newly added limitation. The citation does not provide, however, support for the step of analyzing the result of expression of a protein whose *expression* has been modified (as is recited in step (a) of the claim) by correlating "the modified protein" to the result of expression of a corresponding native protein. The citation merely provides support for the added step in conjunction with a method of modifying a nucleic acid segment to modulate the *result of expression* (i.e. modifying the expressed polypeptide) such that a *modified* protein is expressed. The rejected claim does not recite that the expressed protein is modified in any way, only that expression of the protein is modulated upon somatic gene transfer. Thus, there is no support in the citation provided by applicant's response for inserting the new limitation into the method recited in rejected claim 32. Nor has the examiner identified such support elsewhere in the originally filed claims and specification. Therefore, the newly added limitation is impermissible NEW MATTER.

Claim 46 is further rejected on the grounds that the newly added limitation "...using natural products testing, synthetic chemical testing, combinatorial chemistry, targeted diversity, rational drug design or selective gene suppression techniques..." does not find support in the originally filed claims and specification. Applicant's response does not point anywhere in the originally filed claims and specification for support for the newly added limitation, merely

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indicating that claim 46 has been amended to address a matter of form. The examiner has not been able to identify where in the originally filed specification and claims there is support for the recited Markush group of techniques in relation to the method recited in claim 32, upon which claim 46 depends. Therefore, the newly added limitation for claim 46 is impermissible NEW MATTER.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

Claims 32-36 and 38-64 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **These are new grounds of rejection that were necessitated by applicant's amendment of the claims in the response filed on 1/21/2005.**

Claim 32 is vague and indefinite in that it recites two alternative outcomes in the preamble of the claim without reciting any positive action step that might distinguish between the two different outcomes. This makes it unclear as to what additional steps are required in order to satisfy the different limitations recited in the preamble of the claim. Alternatively, the preamble as currently written suggests that there may be no difference in outcome. If two distinct outcomes are intended for the recited method, it would be remedial to amend the claim to clearly indicate what additional steps are required in order to achieve the two different outcomes. If the outcome of the method is necessarily the same, then it would be remedial to amend the claim to specify a single outcome.

Claim 32 is vague and indefinite in that there is no clear and positive antecedent basis for the term “the modified protein” in part (c) of the claim. There is no indication anywhere previous to step (c) of a “modified” protein (i.e. a protein whose structure has been modified).

Likewise, there is no clear and positive prior antecedent basis in claim 32 for the phrase “the result of expression mimics one or more of the effects of the drug candidate compound”. At least two different genes are expressed in the amended claim, making it unclear which gene is referred to by the phrase. Upon reading the specification, it appears that it would be remedial to amend the claim to clearly indicate that it is the gene whose expression is modulated that mimics the effects of the drug candidate compound. The phrase is also vague and indefinite in that claim recites that the modulation of the expression of the protein in the host cell *necessarily* mimics the effects of the drug candidate compound. If the compound is a *candidate* drug compound, then there is at least a possibility that it will not affect the functional activity of the target gene.

Claim 32 is further vague and indefinite in that the metes and bounds of the term “corresponding native protein” are unclear. The specification does not define this term explicitly and thus leaves it open to interpretation. This makes it unclear in what manner and to what degree the native protein must correspond to the “modified” protein. Must the “corresponding” native protein be the exact same protein that was used to obtain the “modified” protein or can it be a protein that is merely similar in some regard to function to the “modified” protein?

Claim 46 is vague and indefinite in that it recites a step of screening the potential drug target protein using “targeted diversity”, “rational drug design” and “selective gene suppression techniques”. These are somewhat subjective terms that are not clearly defined in the instant

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specification, making it unclear exactly what screening techniques are, and are not, encompassed by these terms.

### ***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G. Leffers Jr., PhD whose telephone number is (571) 272-0772. The examiner can normally be reached on 6:30-4:00.

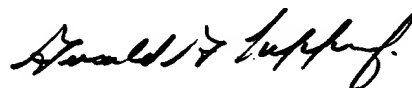
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gerald G Leffers Jr., PhD  
Primary Examiner  
Art Unit 1636

ggl



GERRY LEFFERS  
PRIMARY EXAMINER